What is claimed is:

1. A pharmaceutical formulation comprising (1) an inner solid particulate phase, and (2) an outer solid continuous phase in which particles of the inner solid particulate phase are dispersed and embedded, the particles of the inner solid particulate phase comprising (a) a pharmaceutical having a high water solubility; and (b) an extended release material, and the outer solid continuous phase comprising an extended release material, wherein the total extended release material content in both the inner solid particulate phase and the outer solid continuous phase is within the range more than about 30 by weight of the pharmaceutical formulation.

2. The pharmaceutical formulation as defined in Claim 1 which is a biphasic heterogeneous controlled release formulation which is designed to release pharmaceutical from the particles forming the inner solid particulate phase through the outer solid continuous phase into the upper gastrointestinal tract.

3. The pharmaceutical formulation as defined in Claim 1 wherein the pharmaceutical is metformin or a pharmaceutically acceptable salt thereof.

4. The pharmaceutical formulation as defined in Claim 1 wherein the total extended release material content in both the inner solid particulate phase and the outer solid continuous phase is within the range from about 25 to about 75% by weight of the pharmaceutical formulation.

5. The pharmaceutical formulation as defined in Claim 3 wherein the pharmaceutical is metformin hydrochloride.

6. The pharmaceutical formulation as defined in Claim 1 wherein the extended release material present in the inner solid particulate phase is different from the extended release material present in the outer solid continuous phase.

7. The pharmaceutical formulation as defined in Claim 1 wherein the total extended release material content in both the inner solid particulate phase and the outer solid continuous phase is within the range from about 30 to about 65% by weight of the pharmaceutical formulation.

8. The pharmaceutical formulation as defined in Claim 4 wherein the inner solid particulate phase contains from about 5 to about 95% extended release material based on the weight of the inner solid particulate phase, and the outer solid continuous phase contains from about 40 to about 100% extended release material based on the weight of the outer solid continuous phase.

9. The pharmaceutical formulation as defined in Claim 3 which when ingested by a human reduces maximum attained plasma-metformin concentration (Cmax) by at least about 15% (relative to marketed rapid-release metformin formulations), and increases time to reach maximum metformin-plasma concentration (Tmax) by at least about 30% (relative to marketed rapid-release metformin formulations), while having an insignificant effect on area under the plasma-metformin concentration time curve (AUC) and % urinary recovery (UR) of the dose of metformin (relative to marketed rapid-release metformin formulations).

10. The pharmaceutical formulation as defined in Claim 1 comprising metformin in a therapeutically effective amount which allows a patient a dosing regimen of at least one gram metformin, or a pharmaceutically acceptable salt thereof, once daily, while providing effective control of plasma glucose.

11. The pharmaceutical formulation as defined in Claim 10 in the form of one or more tablets and/or one or more capsules.

12. The pharmaceutical formulation as defined in Claim 10 which provides for a dosing regimen of from about 1 to about 3 grams once daily.

13. The pharmaceutical formulation as defined in Claim 10 wherein the inner solid particulate phase is in the form of discrete individual particles or granules and the outer solid continuous phase is a substantially continuous matrix having individual particles forming the inner solid particulate phase embedded therein and dispersed throughout.

14. The pharmaceutical formulation as defined in Claim 10 which when ingested by a human reduces maximum attained plasma-metformin concentration (Cmax) by at least about 15% (relative to marketed rapid-release metformin formulations), and increases time to reach maximum metformin-plasma concentration (Tmax) by at least about 30% (relative to marketed rapid-release metformin formulations), while having an insignificant effect on area under the plasma-metformin concentration time curve (AUC) and % urinary recovery (UR) of the dose of metformin (relative to marketed rapid-release metformin formulations).

15. The pharmaceutical formulation as defined in Claim 1 wherein the metformin is metformin (2:1) fumarate.

16. The pharmaceutical formulation as defined in Claim 1 wherein the pharmaceutical has a solubility in water of at least about 100 mg/ml and a limited window of absorption in the upper gastrointestinal tract.

17. The pharmaceutical formulation as defined in Claim 1 wherein the pharmaceutical present in the inner solid particulate phase is metformin or a pharmaceutically acceptable salt thereof.

18. The pharmaceutical formulation as defined in Claim 1 wherein the inner solid particulate phase is present in a weight ratio to the outer solid continuous phase within the range from about 0.5:1, to about 4:1.

19. The pharmaceutical formulation as defined in Claim 1 wherein the pharmaceutical is present in the inner solid particulate phase in an amount within the range from about 10 to about 98% by weight of the inner solid particulate phase.

20. The pharmaceutical formulation as defined in Claim 1 wherein the extended release material present in the inner solid particulate phase comprises one or more hydrophilic polymers, one or more hydrophobic polymers and/or one or more other type hydrophobic materials; and the extended release material in the outer solid continuous phase comprises one or more hydrophilic polymers, one or more hydrophobic polymers and/or one or more other type hydrophobic materials.

21. The pharmaceutical formulation as defined in Claim 20 wherein the extended release material present in the inner solid particulate phase comprises one or more ionic polymers and the extended release material present in the outer solid continuous phase comprises one or more non-ionic polymers.

22. The pharmaceutical formulation as defined in Claim 21 wherein the ionic polymer comprises sodium alginate, carbomer, calcium carboxymethylcellulose or sodium carboxymethylcellulose, and the non-ionic polymer comprises hydroxypropylmethylcellulose 2910 USP, viscosity grade ranging from about 4000 to about 100,000 cps and/or hydroxypropylmethyl cellulose 2208 USP viscosity grade ranging from about 3 to about 150 cps.

23. The pharmaceutical formulation as defined in Claim 1 wherein the inner solid particulate phase has a mean particle size within the range from about 30 μm to about 0.8 mm.

24. The pharmaceutical formulation as defined in Claim 1 wherein the inner solid particulate phase comprises metformin, metformin hydrochloride, metformin succinate (2:1) salt or metformin fumarate (2:1) salt, and ethyl cellulose and/or sodium carboxymethyl cellulose

and/or glycerylmonostearate and the outer solid continuous phase comprises hydroxypropylmethylcellulose 2208 USP (100,000 cps), and/or hydroxypropylmethylcellulose 2910 USP (5 cps) and/or microcrystalline cellulose.

25. The pharmaceutical formulation as defined in Claim 1 wherein the pharmaceutical is a combination of metformin or a pharmaceutically acceptable salt thereof and another antihyperglycemic agent and/or a hypolipidemic agent.

26. The pharmaceutical formulation as defined in Claim 1 further including another antihyperglycemic agent and/or a hypolipidemic agent.

27. The pharmaceutical formulation as defined in Claim 26 wherein the other antihyperglycemic agent is a sulfonyl urea, a glucosidase inhibitor, a thiazolidenedione, insulin, or glucogon-like peptide-1.

28. The pharmaceutical formulation as defined in Claim 26 wherein the other antihyperglycemic agent is glyburide, glipizide, pioglitazone or rosiglitazone.

29. The pharmaceutical formulation as defined in Claim 26 wherein the hypolipidemic agent is an MTP inhibitor, a squalene synthetase inhibitor, and HMG CoA reductase inhibitor, a fibric acid derivative, an ACAT inhibitor, a cholesterol absorption inhibitor, an ileal Na^{+}/bile cotransporter inhibitor, a bile acid sequestrant and/or nicotinic acid or a derivative thereof.

30. The pharmaceutical formulation as defined in Claim 26 wherein the hypolipidemic agent is pravastatin, simvastatin, lovastatin, atorvastatin, fluvastatin or cerivastatin.

31. The pharmaceutical formulation as defined in Claim 26 wherein the metformin is present in a weight ratio to the other antihyperglycemic agent or hypolipidemic agent within the range from about 0.01:1 to about 300:1.

32. A method for preparing the pharmaceutical formulation as defined in Claim 1 in the form of a biphasic controlled release delivery system, which comprises forming an inner solid particulate phase comprising individual particles comprising metformin or a pharmaceutically acceptable salt thereof and an extended release material and mixing the individual particles forming the inner solid particulate phase with an outer solid continuous phase comprising an extended release material to thereby disperse and embed the individual particles forming the inner solid particulate phase in the outer solid continuous phase.

33. A biphasic controlled release delivery system formed by the method as defined in Claim 32.

34. A method for treating diabetes which comprises administering once daily to a mammalian patient in need of treatment a therapeutically effective amount of the formulation as defined in Claim 1.

35. A method for treating diabetes, which comprises administering once daily to a mammalian patient in need of treatment a therapeutically effective amount of a formulation as defined in Claim 1.

36. A method for treating diabetes which comprises administering once daily to a mammalian patient in need of treatment a therapeutically effective amount of a formulation as defined in Claim 26.

37. A method for lowering insulin resistance, which comprises administering once daily to a mammalian patient in need of treatment a therapeutically effective amount of the formulation as defined in Claim 1.

38. A method for lowering insulin resistance, which comprises administering once daily to a mammalian patient in need of treatment a therapeutically effective amount of a formulation as defined in Claim 3.

39. A method for lowering insulin resistance, which comprises administering once daily to a mammalian

patient in need of treatment a therapeutically effective amount of a formulation as defined in Claim 26.

40. A pharmaceutical formulation comprising metformin in a therapeutically effective amount which allows a patient a dosing regimen of at least one gram metformin, or a pharmaceutically acceptable salt thereof, once daily, while providing effective control of plasma glucose.

41. The pharmaceutical formulation as defined in Claim 40 in the form of one or more tablets and/or one or more capsules.

42. The pharmaceutical formulation as defined in Claim 40 which provides for a dosing regimen of from about 1 to about 3 grams once daily.

43. The pharmaceutical formulation as defined in Claim 40 comprising (1) an inner solid particulate phase, and (2) an outer solid continuous phase in which particles of the inner solid particulate phase are dispersed and embedded, the particles of the inner solid particulate phase comprising (a) metformin; and (b) an extended release material, and the outer solid continuous phase comprising an extended release material, wherein the extended release material present in the inner solid particulate phase is different from the extended release material present in the outer solid continuous phase and wherein the total extended release material content in both the inner solid particulate phase and the outer solid continuous phase is within the range from about 25 to about 75% by weight of the pharmaceutical formulation.

44. The pharmaceutical formulation as defined in Claim 43 which is a biphasic heterogeneous controlled release formulation which is designed to release metformin from the particles forming the inner solid particulate phase through the outer solid continuous phase into the upper gastrointestinal tract.

45. The pharmaceutical formulation as defined in Claim 43 wherein the metformin is metformin hydrochloride.

46. The pharmaceutical formulation as defined in Claim 43 wherein the total extended release material content in both the inner solid particulate phase and the outer solid continuous phase is within the range from about 30 to about 65% by weight of the pharmaceutical formulation.

47. The pharmaceutical formulation as defined in Claim 43 wherein the inner solid particulate phase contains from about 5 to about 95% extended release material based on the weight of the inner solid particulate phase.

48. The pharmaceutical formulation as defined in Claim 43 wherein the outer solid continuous phase contains from about 40 to about 100% extended release material based on the weight of the outer solid continuous phase.

49. The pharmaceutical formulation as defined in Claim 43 wherein the inner solid particulate phase is in the form of discrete individual particles or granules and the outer solid continuous phase is a substantially continuous matrix having individual particles forming the inner solid particulate phase embedded therein and dispersed throughout.

50. The pharmaceutical formulation as defined in Claim 40 wherein the metformin is metformin hydrochloride.

51. The pharmaceutical formulation as defined in Claim 40 wherein the metformin is metformin (2:1) fumarate.

52. The pharmaceutical formulation as defined in Claim 43 wherein the inner solid particulate phase is present in a weight ratio to the outer solid continuous phase within the range from about 0.5:1, to about 4:1.

53. The pharmaceutical formulation as defined in Claim 43 wherein the metformin is present in the inner solid particulate phase in an amount within the range from about 10 to about 98% by weight of the inner solid particulate phase.

54. The pharmaceutical formulation as defined in Claim 43 wherein the extended release material present in the inner solid particulate phase comprises one or more hydrophilic polymers, one or more hydrophobic polymers and/or one or more other type hydrophobic materials; and the extended release material in the outer solid continuous phase comprises one or more hydrophilic polymers, one or more hydrophobic polymers and/or one or more other type hydrophobic materials.

55. The pharmaceutical formulation as defined in Claim 54 wherein the extended release material present in the inner solid particulate phase comprises one or more ionic polymers and the extended release material present in the outer solid continuous phase comprises one or more non-ionic polymers.

56. The pharmaceutical formulation as defined in Claim 55 wherein the ionic polymer comprises sodium alginate, carbomer, calcium carboxymethylcellulose or sodium carboxymethylcellulose, and the non-ionic polymer comprises hydroxypropylmethylcellulose 2910 USP, viscosity grade ranging from about 4000 to about 100,000 cps and/or hydroxypropylmethyl cellulose 2208 USP viscosity grade ranging from about 3 to about 150 cps.

57. The pharmaceutical formulation as defined in Claim 43 wherein the inner solid particulate phase has a mean particle size within the range from about 30 mm to about 0.8 mm.

58. The pharmaceutical formulation as defined in Claim 43 wherein the inner solid particulate phase comprises metformin, metformin hydrochloride, metformin succinate (2:1) salt or metformin fumarate (2:1) salt, and ethyl cellulose and/or sodium carboxymethyl cellulose

and/or glycerylmonostearate and the outer solid continuous phase comprises hydroxypropylmethylcellulose 2208 USP (100,000 cps), and/or hydroxypropylmethylcellulose 2910 USP (5 cps) and/or microcrystalline cellulose.

59. The pharmaceutical formulation as defined in Claim 40 further including another antihyperglycemic agent and/or a hypolipidemic agent.

60. The pharmaceutical formulation as defined in Claim 59 wherein the other antihyperglycemic agent is a sulfonyl urea, a glucosidase inhibitor, a thiazolidenedione, insulin, or glucogon-like peptide-1.

61. The pharmaceutical formulation as defined in Claim 59 wherein the other antihyperglycemic agent is glyburide, glipizide, pioglitazone or rosiglitazone.

62. The pharmaceutical formulation as defined in Claim 59 wherein the hypolipidemic agent is an MTP inhibitor, a squalene synthetase inhibitor, and HMG CoA reductase inhibitor, a fibric acid derivative, an ACAT inhibitor, a cholesterol absorption inhibitor, an ileal Na^{+}/bile cotransporter inhibitor, a bile acid sequestrant and/or nicotinic acid or a derivative thereof.

63. The pharmaceutical formulation as defined in Claim 59 wherein the hypolipidemic agent is pravastatin, simvastatin, lovastatin, atorvastatin, fluvastatin or cerivastatin.

64. The pharmaceutical formulation as defined in Claim 40 which when ingested by a human reduces maximum attained plasma-metformin concentration (Cmax) by at least about 15% (relative to marketed rapid-release metformin formulations), and increases time to reach maximum metformin-plasma concentration (Tmax) by at least about 30% (relative to marketed rapid-release metformin formulations), while having an insignificant effect on area under the plasma-metformin concentration time curve (AUC) and % urinary recovery (UR) of the dose of

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metformin (relative to marketed rapid-release metformin formulations).

65. A method for treating diabetes which comprises administering once daily to a mammalian patient in need of treatment a therapeutically effective amount of the formulation as defined in Claim 3.

66. A method for treating diabetes, which comprises administering once daily to a mammalian patient in need of treatment a therapeutically effective amount of a formulation as defined in Claim 40.

67. A method for treating diabetes which comprises administering once daily to a mammalian patient in need of treatment a therapeutically effective amount of a formulation as defined in Claim 59.

68. A method for lowering insulin resistance, which comprises administering once daily to a mammalian patient in need of treatment a therapeutically effective amount of the formulation as defined in Claim 3.

69. A method for lowering insulin resistance, which comprises administering once daily to a mammalian patient in need of treatment a therapeutically effective amount of a formulation as defined in Claim 40.

70. A method for lowering insulin resistance, which comprises administering once daily to a mammalian patient in need of treatment a therapeutically effective amount of a formulation as defined in Claim 59.

71. A pharmaceutical formulation comprising (1) an inner solid particulate phase, and (2) an outer solid continuous phase in which particles of the inner solid particulate phase are dispersed and embedded, the particles of the inner solid particulate phase comprising (a) a pharmaceutical having a high water solubility; and (b) an extended release material, and the outer solid continuous phase comprising an extended release material.